

The world's first female sex drug could spur similar meds

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In this Aug. 18, 2015 file photo, Sprout Pharmaceuticals CEO Cindy Whitehead holds a bottle for the female sex-drive drug Addyi at her Raleigh, N.C. Most women with low sexual desire won't rush out to get the first prescription drug to boost female libido when it launches on Saturday, Oct. 17, 2015. But they may have more options down the road. (AP Photo/Allen G. Breed)

Most women with low sexual desire won't rush to get the first

prescription drug to boost female libido when it becomes available on Saturday. But they may have more options down the road.

Addyi can't be taken with alcohol or certain other medications, which will likely limit its use. But experts believe those restrictions could spur development of better treatments for [women's sexual problems](#) after more than a decade of neglect by most of the world's large drugmakers.

Kim Wallen, a [psychology professor](#) at Emory University, says Addyi represents a historic milestone that may open the door to more drugs targeting desire in men and women. Where Viagra and other men's erectile dysfunction drugs work by increasing blood flow to the genitals, Addyi acts on brain chemicals associated with desire.

"This is the first time that a [drug](#), for either men or women, has been approved strictly to increase sexual desire," Wallen says. "That legitimizes many other drugs that are in development."

Treatments for women's libido issues are an untapped financial opportunity for drugmakers. Analysts estimate the market could be worth over \$2 billion, based on academic estimates that between 5 million and 9 million U.S. women may suffer from desire disorders.

But the area hasn't been a research priority for drugmakers in many years. Beginning in the 1990s, Pfizer, Bayer and Procter & Gamble all studied—then discarded—drugs targeting female libido.

Addyi itself was developed by the German conglomerate, Boehringer Ingelheim, then sold to Sprout Pharmaceuticals after the Food and Drug Administration rejected the medication due to lackluster effectiveness and issues like nausea, fatigue and dizziness.

It took Sprout four years to win FDA approval for Addyi, which acts on

brain chemicals associated with mood and appetite. The drug will come with a bold warning label about the risks of fainting if combined with alcohol or certain medications. Additionally, doctors and pharmacists must complete an online certification process to show they understand the drug's risks.

Dr. Lisa Dabney says several patients have asked her about Addyi, but they generally lose interest after she explains they cannot drink alcohol while taking the daily medication.

"It's definitely an option that's going to help patients," says Dabney, of New York's Mt. Sinai hospital. "But it's going to have a limited patient audience because of the alcohol restrictions and the fact that you have to take it every day."

Still, some women credit the drug with saving their relationships.

Amanda Parrish, 52, had been married for three years when she realized she was avoiding sex with her husband. Her doctor said it was natural to lose sexual interest with age and suggested she try a vibrator. But nothing worked until Parrish enrolled in a trial of Addyi, which was studied in women who report distress due to a lack of libido.

"It just brought me back to where I was as far as being flirty and playful," says Parrish, who lives in Nashville. "I went back to the days of leaving notes on his window, in his car, on his mirror in the morning."

Experts generally describe Addyi's effect as "modest." In company studies, women taking the drug that's also called flibanserin reported a slight uptick in sexually satisfying events each month. Their answers to separate questionnaires indicated they experienced a slight increase in desire and a slight decrease in stress.

Analysts from Evercore ISI estimate Addyi could generate sales of \$200 million annually. That's far below the blockbuster numbers once discussed by experts and the \$1 billion that Valeant Pharmaceuticals recently agreed to purchase Sprout.

But the buyout has revived interest in a handful of competitors developing alternate treatments. Those products include nasal sprays, injections and antidepressant pills.

It could be years before any of them reach patients. That's because the field of women's sexual medicine remains a small one, comprised of tiny companies with limited resources.

Leading the field is Cranbury, N.J.-based Palatin Technologies Inc. which is studying an injectable drug that mimics a hormone linked to sexual arousal.

Unlike Addyi, women would only take the drug when they want to be sexually active. The company's pen-like injector contains a single dose of bremelanotide, which lasts about eight hours. Where Addyi is absorbed into the entire nervous system, Palatin drug's targets a specific region of the brain.

Mid-stage trial results suggest the drug could be at least as effective as Addyi without the dangerous interactions with alcohol. Palatin hopes to submit its drug to the FDA in 2017 with a decision in 2018.

Wall Street analysts estimate the drug, if approved, could reach sales around \$500 million, according to Piper Jaffray.

In interviews, company executives highlight the differences between their drug and Addyi. But they also acknowledge the trailblazing path paved by their competitor. Palatin CEO Carl Spana says larger

drugmakers are again interested in discussing partnerships with his company, after years of doubts about the future of female sex drugs.

"With the approval of Addyi that's changed and we've seen a much larger uptick in the number of companies that want to talk to us," Spana says.

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